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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/324,343	06/02/99	GEERKE J	ARC-2865-R3

HM12/0313

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EXAMINER	
SHARAREH, S	
ART UNIT	**PAPER NUMBER**
1619	11

DATE MAILED: 03/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/324,343	Geerke
Examiner	**Group Art Unit**
Shahnam Sharar h	1619

☒ Responsive to communication(s) filed on *Dec 19, 2000*

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-31* is/are pending in the applicat

Of the above, claim(s) *1-17* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *18-31* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-17* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachm nt(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Amendment filed on December 19, 2000 has been entered. Claims 18-23, 25, 27-28, 30 are amended. Claims 1-17 stand withdrawn from further consideration because they are directed to a non-elected invention. This application contains claims 1-17 drawn to an invention nonelected with traverse in Paper No. 5. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Claims 1-31 are pending.

Response to Arguments

2. Applicant's arguments with respect to the rejection of claims 18-31 under 35 U.S.C. 102 as being anticipated by Hoover et al US Patent 5,464,631 have been fully considered and are found persuasive in view of the amended claims. Hoover does not teach multi layer osmotic tablets. This rejection is withdrawn.

3. Applicant's arguments with respect to the rejection of claims 18-31 under 35 U.S.C. 103(a) as being unpatentable over Hoover et al US Patent 5,464,631 in view of Wong et al US Patent 5,785,994 have been considered and are found partially persuasive in view of the amendments. Accordingly the rejection of claims 18-21 are withdrawn. However claims 22-31 stand rejected.

The rejected claims are directed to three layer tablet comprising a first layer formulation containing a drug ingredient and a second layer containing a drug ingredient, wherein one of said

first or second layers also containing a first colorant, and a third layer containing a second colorant that is distinguishable from first colorant or from no color.

The instant contrast agents appear to be drafted as "product by process" claims. Accordingly, product by process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps (see MPEP 2113.) "Even though product - by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product - by - process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe , 227 USPQ 964, 966 (Fed. Cir. 1985). Therefore, determining the patentability of the instant three layer tablet are based on the components of the instant formulation not the steps of making them.

As discussed in page 3 of the Office Action filed on June 6, 2000, Hoover clearly teaches compressed multi layer tablets comprising different layers having different colorants. The tablets of Hoover contains multiple colorants compressed with the active agent into a dosage form (col 6 lines 45-67). Hoover also teaches preparing sustained release dosage forms of similar type of composition by various material known in the art (col 5 lines 34-44). Hoover lacks the specific teaching of an osmotic tablet having an orifice, but such teachings are provided by Wong.

Wong et al disclose tablet dosage forms comprising three layers wherein first layer is drug free, either first or second layer comprise a colorant such as ferric oxide (see col 17 line 23), and

the third layer comprise a colorant (see figure 3, col 16 lines 58-67, col 18 lines 1-42). The tablet of Wong comprise an exit port (see col 17 line 56) which is drilled by any means known in the art such as laser drilling (see col 15 lines 15-18). Wong et al disclose that their tablets are prepared by pressing the three layers to form a solid core (see col 19 lines 10-18). Wong et al fail to specifically disclose the use of various coloring agents in different layers of his tablet.

Therefore, preparing a sustain release dosage form as suggested by Hoover would have been obvious using Wong's methods, because ~~an~~ one of ordinary skill in the art would have had a reasonable expectation to succeed in formulating dosage forms that provide a sustained release tamper-resistant formulation that possess the physical characteristics of a capsule and allows easier swallowing, and masking the bitter taste of drugs. 3-01

In response to applicant's argument that Wong does not teach detection of formulation orientation by means of color detector, Examiner states the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). As stated above, one of ordinary skill in the art would have had reasonable expectation of success combining the teachings of Hoover and Wang.

New Grounds of Rejection

4. Claims 18-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoover et al US Patent 5,464,631 and Jacobs et al US Patent 5,824,338 (IDS 6/1999) in view of Wong et al

US Patent 5,785,994 further in view of Nagashima et al US Patent 5,094,786 (IDS 6/1999) , Weier US Patent 5,558,231 (IDS 6/1999), or Misra et al US Patent 5,422,831 (IDS 6/1999).

The teachings of Hoover and Wong are discussed previously. Jacobs is used to indicate the state of art with respect to the use of colorant in making caplets (capsule shaped tablets). According to Jacobs caplet layers such as gelatin coating can be clear or colored in matching or different colors to provide the desired appearance of the resultant medicament to identify the medication contained within the cover and to provide a pleasing aesthetic appearance to the medicament (col 4 lines 5-10). Therefore, the multi utility of colorant to prepare an aesthetic appearance as described by Hoover, and identifying the medication contained within the layers is well recognized in the art.

Nagashima et al, Weier and Misra et al are all use to show various conventional methods of studying the characteristics of pharmaceutical compositions using light and imaging systems. For example, Nagashima shows detection of defects within a multi layer tablets using a light source (abstract, col 10 lines 64-68, col 11 lines 1-10). Weier teaches methods of assorting dosage forms according to the form and color of the dosage forms (abstract). Weier teaches methods of detecting color errors, coating errors, etc using light beams reflected from small surface areas of the dosage forms (col 3 lines 10-33, 60-67). Similarly, Misra teaches methods of determining the quality of pharmaceutical products based on physical characteristics such as shape, hardness, color and surface (col 3 lines 29-40) using transducer signals. Misra teaches

analysis of the color of the pills and detection of undesirable characteristics of a given dosage form (col 11 lines 5-50, col 13 lines 1-24).

The teachings of Hoover, Jacobs and Wong are not directed to detection of physical characteristics of a dosage form such as a multi layer osmotic caplet, but as discussed above the combined teachings of Hoover, Jacobs and Wong renders the use of colorants in different layers of an osmotic dosage forms obvious. Since methods of determining color characteristics of dosage forms by a detector, as taught by Nagashima et al, Weier or Misra, are conventional; it would have been obvious to one of ordinary skill in the art at the time of invention to formulate a multi layer osmotic dosage form having different color in each layer, as described by Hoover and Wong, and then study its physical characteristics as taught by the teachings of Nagashima et al, Weier or Misra to determine accurate measures of any desirable physical characteristic such as formulation orientations.

Conclusion

5. No claims are allowed. Applicant is requested to provide a clean copy of all pending claim in reply to this Office Action.

Applicant's amendment modified the scope of the independent claims, thus necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Jose Dees can be reached on 703-308-4628. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

sjs 3/7/01

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